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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,288	09/11/2003	Michael Zung	6771USP4	5342

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ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER

LYNCH, ROBERT A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/660,288	Applicant(s) ZUNG ET AL.	
	Examiner Robert A. Lynch	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 21-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/18/04; 3/4/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-20, drawn to a suturing device, classified in class 606, subclass 144.
 - II. Claims 21-29, drawn to a method of suturing tissue, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as for use in the textile industry for stitching together two pieces of fabric.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Kelly J. McCrystle on October 26, 2005, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "692" in Figure 51. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-3, 5, 7, 11-14, 16 and 18** are rejected under 35 U.S.C. 102(b) as being anticipated by Violante (U.S. 3,840,017).

Regarding **claim 1**, Violante discloses a housing (170), a needle (164) movable with respect to the housing (column 3, line 33-column 4, line 3), the needle being attached to a length of suture (160), and a suture cutting blade (176) positioned on the device such that when the needle is withdrawn from the device, the suture can be drawn across the blade to sever the suture (see Figs. 13-15).

Regarding **claim 2**, Violante discloses the blade (176) being mounted on the housing (170) (see Figs. 13-15).

Regarding **claim 3**, Violante discloses the housing (170) having a distal end (near cross-section 14) and a proximal end (near cross-section 15), and the blade (176) being positioned near the distal end (see Fig. 13).

Regarding **claim 5**, Violante discloses the needle (164) and the suture (160) being withdrawn from the proximal end (near cross-section 15) of the housing (170) (see Fig. 13; and column 3, line 33-column 4, line 3).

Regarding **claim 7**, Violante discloses the blade (176) being mounted on the outside of the housing (170) (see Figs. 13-15).

Regarding **claim 11**, Violante discloses the needle (164) having a distal end (see tip of needle 164) and the suture (160) being attached to the distal end of the needle (see Fig. 13).

Regarding **claim 12**, Violante discloses a housing (170) having a proximal end (near cross-section 15) and a distal end (near cross-section 14); a suture cutting blade (176) positioned on the housing; an elongate shaft (172) extending from the distal end of the housing, the elongate shaft having a distal end region (near cross-section 14); a needle actuation handle (157) movable through the proximal end of the housing (174 movable through proximal end of 170); a needle (164) extending from the needle actuation handle (157), through the housing (170) and further through the shaft (172); and a suture (160) carried by the device, wherein a portion of the suture (160) is positioned near the distal end region (near cross-section 14) of the shaft (172) such that the needle (176) pulls the suture (160) proximally to position the suture through tissue.

Regarding **claim 13**, Violante discloses the blade (176) being positioned near the distal end (near cross-section 14) of the housing (170) (see Fig. 13).

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Regarding **claim 14**, Violante discloses the needle (164) pulling the suture (160) through the proximal end (near cross-section 15) of the housing (170) (see Fig. 13; and column 3, line 33-column 4, line 3).

Regarding **claim 16**, Violante discloses the needle (164) and the suture (160) being withdrawn from the proximal end (near cross-section 15) of the housing (170) (see Fig. 13; and column 3, line 33-column 4, line 3).

Regarding **claim 18**, Violante discloses the blade (176) being mounted on the outside of the housing (170) (see Figs. 13-15).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 4, 6, 8-10, 15, 17, 19 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Violante in view of Ogburn (U.S. RE 22,857).

Violante discloses the invention substantially as claimed, including a removable housing (170) that will be handled and gripped by the operator's fingers when it is moved both onto and off of the body (157) of the surgical instrument. Violante does not disclose the blade being positioned in the distal opening (opening of bore (172) near cross-section 14), near the proximal end of the housing, on the inner surface (172) of the hollow housing, on a finger grip (170), or on a movable handle (170).

However, *In re Japikse*, held that claims that read on the prior art except with regard to the position of a claimed element were held unpatentable if shifting the position of the claimed element would not have modified the operation of the device. 181 F.2d 1019, 86 USPQ 70 (CCPA 1950). Simple relocation of the suture-cutting blade does not modify the operation of the claimed device, but merely relocates the location of drawing the suture across the blade.

Furthermore, Ogburn discloses that it is old and well known in the art to use a stationary suture cutting blade on the housing of a medical suturing device for the purpose of severing the suture after it has been applied to the wound (column 1, lines 29-32; column 2, lines 11-13; and column 4, lines 3-10; see Figs. 1-3 and 11-13, reference numerals 51-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stationary suture cutting blade on the housing of the device of Violante, in order to gain the advantage of being able to sever the suture after it has been applied to the wound, as taught by Ogburn.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pertinent prior art includes Fischbein (U.S. 2,941,489) disclosing a device having stationary blade for cutting thread, Bates et al. (U.S. 3,197,102) disclosing a thread support having a fixed cutting member, Lawrence (U.S. 6,048,354) disclosing a surgical device having a housing that contains a needle and knife blade, and Tal (U.S. 6,716,228) disclosing a needle housing having a blade attach along the length of the housing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Lynch whose telephone number is (571) 272-6465. The examiner can normally be reached on Monday-Friday 8AM to 5PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RL


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
01/12/05.